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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,858	08/11/2005	Hideaki Yamaoka	10921.264USWO	5820
52835	7590	10/17/2006	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/518,858	YAMAOKA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bin Shen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 8-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>          </u> | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1655

**DETAILED ACTION**

The IDS received 12/17/2004, 8/24/2006 have been entered.

***Election***

Applicant's election with traverse of Group I, claims 1-7, in the reply filed on 9/14/2006 is acknowledged. The traversal is on the ground(s) that all the claims require the combination of glucose dehydrogenase and Ru compound and that this feature is neither disclosed nor suggested by the prior art, and there is no undue burden in examining the claims. This is not found persuasive because prior art (Reiter et al. see below) discloses the combination of glucose dehydrogenase and Ru compound, and the arguments ("undue burden") are not applicable to lack of unity restriction rules (PCT Rule 13.1).

The requirement is still deemed proper and is therefore made FINAL.

Applicants also request that Groups II-III be rejoined with Group I upon allowance, but Group I is not a product, thus rejoinder is not proper.

Claims 8-32 are nonelected and thus are withdrawn from further consideration.

Claims 1-7 are presented for examination on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

Art Unit: 1655

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the Ru compounds represented by a chemical formula  $[\text{Ru}(\text{NH}_3)_5\text{X}]^{n+}$  does not reasonably provide enablement for any and all Ru compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all Ru compound to see if they can be used as electron carrier. There is no prior art known to this examiner that establishes that one of ordinary skill in the art would have known at the time the invention was made that all or any of the Ru compound can be used as electron carrier.

Applicant has only shown in their example the Ru compounds represented by a chemical formula  $[\text{Ru}(\text{NH}_3)_5\text{X}]^{n+}$ , see specification at page 23. With only knowing the Ru compounds represented by a chemical formula  $[\text{Ru}(\text{NH}_3)_5\text{X}]^{n+}$  it is clear that such broad claims are not enabled by the instant specification when one of

Art Unit: 1655

ordinary skill in the art is only given one particular chemical formula that function as electron carrier.

The state of the art is that there is no art. Without any reference to all the Ru compound that function as electron carrier, one of ordinary skill in the art would have no way of knowing if all or any of the Ru compound can be used as the electron carrier.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is incomplete because it lacks a correlating step to accomplish the preamble of the claim.

Art Unit: 1655

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiter et al. (Analyst. 2001;126(11):1912-1918).

Reiter et al. teach a redox reaction with glucose dehydrogenase and Ru compound ( $\text{Ru}(\text{bpy})_2\text{Cl}_2$ , and  $\text{Ru}(\text{bpy})_2\text{CO}_3$ , see abstract), where small aliquots of enzyme solution (read as stimulation in claim 4) have been stepwise added to the reaction, and the response recorded (page 1916, left column, 1<sup>st</sup> full paragraph). Glucose dehydrogenase inherently has three subunits including cytochrome C because Yum et al. teach that all membrane-bound glucose dehydrogenase that have been purified and characterized consist of three subunits, a dehydrogenase ( $\alpha$  subunit), a cytochrome c and a third component of the lowest molecular weight ( $\gamma$  subunit) (page 6571, left column, 2<sup>nd</sup> full paragraph).

Therefore, the cited reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

Art Unit: 1655

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter et al. (Analyst. 2001;126(11):1912-1918), in view of Yum et al. (J Bacteriol. 1997;179(21):6566-6572) and Chen et al. (Anal Chem 2001;73:2862-2868).

Reiter teaches what is above.

Reiter does not teach that the cytochrome C is derived from burkholderia genus, with a molecular weight of about 43 kDa,  $\alpha$  subunit of glucose dehydrogenase with a molecular weight of about 60 kDa, and  $\gamma$  subunit of glucose dehydrogenase with a molecular weight of about 14 kDa, and Ru compound is a complex represented by  $[\text{Ru}(\text{NH}_3)_5\text{X}]^{n+}$ .

Chen et al. teach a method of measuring glucose concentration using glucose oxidase and  $\text{Ru}(\text{NH}_3)_6^{3+}$  cation and a selected anion, such as  $\text{Ru}(\text{CN})_6^{4-}$ ,  $\text{Fe}(\text{CN})_6^{4-}$ ,  $\text{Co}(\text{CN})_6^{3-}$  or  $\text{IrCl}_6^{3-}$  (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Reiter by using the Ru compound taught by Chen because Chen teaches that the composite of Ru compound allows for an interference-free determination of glucose, and that the design of the biocomposites is generic and can incorporate

Art Unit: 1655

oxidoreductase enzymes other than glucose oxidase (such as dehydrogenase) to provide a host of biosensors for biologically and environmentally important analytes (bottom of the abstract and page 2868, Conclusions). One would have been motivated to make the modification because Reiter et al. specifically described the combination of glucose dehydrogenase with Ru complexes and Chen et al. teaches the benefit of using  $[\text{Ru}(\text{NH}_3)_5\text{X}]^{n+}$  as electron carrier, and would reasonably have expected success in view of both Reiter and Chen's teachings. The adjustment of particular conventional working conditions (e.g., specific genus where cytochrome c is derived from, the molecular weight of cytochrome c, molecular weight of  $\alpha$  and  $\gamma$  subunits of glucose dehydrogenase) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

5. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December



Art Unit: 1655

28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Art Unit: 1655

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

  
MICHAEL MELLER  
PRIMARY EXAMINER

*B Shen*

Art Unit 1655